

Message

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**From:** Monika Szablicka [monika.szablicka@envigo.com]  
**Sent:** 5/25/2017 12:44:19 PM  
**To:** Odusote, Gloria [odusote.gloria@epa.gov]  
**CC:** Melissa Elliott [melissa.elliott@envigo.com]  
**Subject:** RE: Concerning Your Case

Dear Gloria,

I am contacting you again for the P-16-0509 case. Unfortunately I can not get hold of the Program Manager Jeff Bauer via phone. Please can you provide me with his phone number?

Thank you.

Best regards  
Monika

Monika Szablicka  
Regulatory Specialist  
T +44 (0) 1480 892 439  
F +44 (0) 1480 892 362  
envigo.com



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**From:** Odusote, Gloria [mailto:odusote.gloria@epa.gov]  
**Sent:** Tuesday, May 16, 2017 6:55 PM  
**To:** Monika Szablicka  
**Subject:** RE: Concerning Your Case

Hi Monika,  
Jeff Bauer is the Program Manager for your case. I'm not sure when the consent order will be developed especially with the current backlog. His phone number is 202-564-9042.

Best regards,  
Gloria

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**From:** Monika Szablicka [mailto:monika.szablicka@envigo.com]  
**Sent:** Tuesday, May 16, 2017 9:30 AM  
**To:** Odusote, Gloria <odusote.gloria@epa.gov>  
**Cc:** Melissa Elliott <melissa.elliott@envigo.com>  
**Subject:** RE: Concerning Your Case

Dear Gloria,

Would it be possible please for you to contact the Program Manager at EPA Rose Allison, for our other PMN which is related to this submission. It is P-16-0509. We have submitted response to the action letter and we understand that the consent order will be issued by June 5<sup>th</sup>. We have however not heard anything from EPA. Please can you confirm this as I am unable to contact our technical contact at the moment.

I would really appreciate your help regarding this.

Thank you.

Kind regards  
Monika

Monika Szablicka  
Regulatory Specialist  
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F +44 (0) 1480 892 362  
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**From:** Monika Szablicka  
**Sent:** Tuesday, May 16, 2017 2:22 PM  
**To:** 'Odusote, Gloria'  
**Subject:** RE: Concerning Your Case

Dear Gloria,

Thank you very much.

Kindest regards  
Monika

Monika Szablicka  
Regulatory Specialist  
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F +44 (0) 1480 892 362  
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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]  
**Sent:** Tuesday, May 16, 2017 1:53 PM  
**To:** Monika Szablicka  
**Subject:** RE: Concerning Your Case

Hi Monika,  
Sure, let me know if there is any way I can help.

Best,  
Gloria

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**From:** Monika Szablicka [<mailto:monika.szablicka@envigo.com>]  
**Sent:** Tuesday, May 16, 2017 8:39 AM  
**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>  
**Subject:** RE: Concerning Your Case

Dear Gloria,

Our client has requested today a suspension of 15 days. Please can you let me know if this is acceptable?

Thank you.

Kind regards  
Monika

Monika Szablicka  
Regulatory Specialist  
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F +44 (0) 1480 892 362  
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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]  
**Sent:** Friday, May 12, 2017 6:58 PM  
**To:** Monika Szablicka  
**Subject:** RE: Concerning Your Case

Hi Monika,  
Please let me know if I misunderstood you but I took your previous message as you asking for a 7 day suspension. Please let me know if that is not the client's request and I can rescind the suspension.

Best regards,  
Gloria

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**From:** Monika Szablicka [<mailto:monika.szablicka@envigo.com>]  
**Sent:** Friday, May 12, 2017 12:39 PM  
**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>  
**Cc:** Melissa Elliott <[melissa.elliott@envigo.com](mailto:melissa.elliott@envigo.com)>  
**Subject:** RE: Concerning Your Case

Dear Gloria,

Thank you very much for your confirmation. I have asked if this data is available. I will keep you updated.

With very best regards  
Monika

Monika Szablicka  
Regulatory Specialist  
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F +44 (0) 1480 892 362  
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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]  
**Sent:** Thursday, May 11, 2017 6:58 PM  
**To:** Szablicka, Monika  
**Subject:** RE: Concerning Your Case

Hi Monika,

A week should be fine, if they think they have monitoring data or equipment information detailing the exposures. I can let you know if you'll need to request another suspension.

Best,  
Gloria

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**From:** Szablicka, Monika [<mailto:monika.szablicka@envigo.com>]  
**Sent:** Thursday, May 11, 2017 10:27 AM  
**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>  
**Subject:** RE: Concerning Your Case

Dear Gloria,

Thank you for contacting me. I am sorry I am not in the office today.  
Today our client informed me that they will be preparing the additional information regarding no inhalation and environmental exposure. They will however need about a week for this. Will this be acceptable to EPA please?

Thank you.  
Kind regards  
Monika

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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]  
**Sent:** 11 May 2017 15:06  
**To:** Szablicka, Monika  
**Subject:** RE: Concerning Your Case

Hi Monika,  
Do you want to call? I am not sure what kind of information the company might want to resubmit and I might be able to give better advice if we deal with the specifics.

Best regards,  
Gloria

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**From:** Szablicka, Monika [<mailto:monika.szablicka@envigo.com>]  
**Sent:** Wednesday, May 10, 2017 11:56 AM  
**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>  
**Subject:** RE: Concerning Your Case

Dear Gloria,

Our client is preparing the final response however they asked me to confirm with you the following:  
If they decide to select Option 3 from the action letter and withdraw the PMN how soon they can re-submit? They are considering changing some information provided in the original PMN. This is very hard decision for them.

Please can you advise?

Thank you.

Kind regards  
Monika

Monika Szablicka  
Regulatory Specialist  
T +44 (0) 1480 892 439



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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]  
**Sent:** Monday, May 08, 2017 7:35 PM  
**To:** Szablicka, Monika  
**Subject:** RE: Concerning Your Case

Hi Monika,

If you provide information that there is no inhalation and environmental exposures, the testing would no longer be upfront.

You would still need to respond to the action letter, checking the option that you are providing more information and giving us the time to review the information and write the consent order.

Best,  
Gloria

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**From:** Szablicka, Monika [<mailto:monika.szablicka@envigo.com>]  
**Sent:** Monday, May 8, 2017 10:14 AM  
**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>  
**Subject:** RE: Concerning Your Case

Dear Gloria,

Thank you very much for your time earlier on. There was one question which I would appreciate you clarification on. If we provide an information that there is no inhalation possibility - would we still need to conduct the studies (OECD 422 and OECD 486)? Would we still have to respond to the action letter?

Thank you  
Kind regards  
Monika  
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Regulatory Specialist  
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---

**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]  
**Sent:** Monday, May 08, 2017 1:31 PM  
**To:** Szablicka, Monika  
**Subject:** RE: Concerning Your Case

Hi Monika,  
I'm free today. Feel free to call anytime.

Best regards,  
Gloria

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**From:** Szablicka, Monika [<mailto:monika.szablicka@envigo.com>]  
**Sent:** Monday, May 8, 2017 8:23 AM  
**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>  
**Cc:** Elliott, Melissa <[melissa.elliott@envigo.com](mailto:melissa.elliott@envigo.com)>  
**Subject:** RE: Concerning Your Case

Dear Gloria,

Please can you let me know if you are available for the call today?

Thank you.

Kind regards

Monika

Monika Szablicka

Regulatory Specialist

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**From:** Szablicka, Monika  
**Sent:** Friday, May 05, 2017 9:49 AM  
**To:** 'Odusote, Gloria'  
**Cc:** Elliott, Melissa  
**Subject:** RE: Concerning Your Case

Dear Gloria,

Please can you let me know when it will be convenient for you so I can call you?

I will be in a meeting until 11am UK time and then between 12.30-14.00pm UK time.

Thank you.

Kind regards

Monika

Monika Szablicka

Regulatory Specialist

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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]  
**Sent:** Thursday, May 04, 2017 7:29 PM  
**To:** Szablicka, Monika  
**Cc:** Elliott, Melissa  
**Subject:** RE: Concerning Your Case

Hi Monica,

In answering this, I would have to explain the test. Since that is CBI, it would probably be best to explain this over the phone.

Best regards,  
Gloria

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**From:** Szablicka, Monika [<mailto:monika.szablicka@envigo.com>]

**Sent:** Thursday, May 4, 2017 11:43 AM

**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>

**Cc:** Elliott, Melissa <[melissa.elliott@envigo.com](mailto:melissa.elliott@envigo.com)>

**Subject:** RE: Concerning Your Case

Dear Gloria,

Thank you for your kind assistance. Our client is considering the regulatory options and they have some queries. Please can you help us understanding the engineering report, i.e. is there a specific part which we should pay attention to?

In the EPA action letter it is stated that there is a concern for acute toxicity however we have submitted the test report on acute toxicity (please refer to Attachment no. 12 in the original PMN). Additionally, and also as stated in the engineering report the compound does not raise concerns regarding mutagenicity or genetic toxicity in vivo and is unlikely to be carcinogenic. We would really appreciate if you could give us more details as to why the OECD 422 and OECD 486 are required?

Our client is also considering an analog substance which could possess any data on the health effects information but it is difficult to identify the appropriate analog.

Another question which our client has is whether we can change the application without selecting these 3 options?

Please can you give us your comments regarding the above?

Thank you.

Kind regards  
Monika

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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]

**Sent:** 27 April 2017 18:09

**To:** Szablicka, Monika

**Cc:** Elliott, Melissa

**Subject:** RE: Concerning Your Case

Hi Monika and Melissa,

Yes, you still have the current suspension and since we have been talking, the suspension applies to the action letter as well. Please let me know if there is any way that I can help speed up the process. With the current changes in the EPA, wrapping up the review time for these chemicals has become a priority.

Best regards,  
Gloria Odusote

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**From:** Szablicka, Monika [<mailto:monika.szablicka@envigo.com>]

**Sent:** Wednesday, April 26, 2017 7:33 AM

**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>; Elliott, Melissa <[melissa.elliott@envigo.com](mailto:melissa.elliott@envigo.com)>

**Subject:** RE: Concerning Your Case

**Importance:** High

Dear Gloria,

I am aware about the two separate 15 day suspensions to allow us for any review and actions from the engineering report. However I think the 30 days response to the EPA action letter (dated Mar27, 2017) ends today please can you therefore confirm that the extension also applies to this? Unfortunately our client is still considering their final decision.

I appreciate your response at your earliest convenience.

Thank you.

Kind regards

Monika

Monika Szablicka  
Regulatory Specialist  
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F +44 (0) 1480 892 362  
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---

**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]

**Sent:** Wednesday, April 12, 2017 1:56 PM

**To:** Szablicka, Monika

**Subject:** RE: Concerning Your Case

Hi Monica,

Do you have the fax number yet? Also your day 90 is coming up. Would you like to request a suspension while you read through the report and come up with the new information?

Bets regards,

Gloria

---

**From:** Szablicka, Monika [<mailto:monika.szablicka@envigo.com>]

**Sent:** Wednesday, April 5, 2017 10:15 AM

**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>

**Subject:** RE: Concerning Your Case

Dear Gloria,

I am sorry for this. I am checking with the technical contact if the fax number is available at her side.

Thank you.

Kind regards

Monika

Monika Szablicka  
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F +44 (0) 1480 892 362  
envigo.com



---

**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]  
**Sent:** Tuesday, April 04, 2017 9:14 PM  
**To:** Szablicka, Monika  
**Subject:** RE: Concerning Your Case

Hi Monica,  
I hope this email finds you well. I have the engineering report for your case. Do you have a domestic fax number?

Best regards,  
Gloria

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**From:** Szablicka, Monika [<mailto:monika.szablicka@envigo.com>]  
**Sent:** Tuesday, March 28, 2017 10:46 AM  
**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>  
**Subject:** RE: Concerning Your Case

Dear Gloria,

Thank you very much for contacting me with respect to our submission.

I will summarize your concerns with regards to the substance and will inform our client respectively while waiting for the official EPA letter.

If I understood correctly, may I request the engineering controls report to be sent to us via fax?  
The number for the fax is: (0044)01480 892362.

Thank you.  
Kind regards  
Monika  
Monika Szablicka  
Regulatory Specialist  
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F +44 (0) 1480 892 362  
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---

**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]  
**Sent:** Tuesday, March 28, 2017 2:09 PM  
**To:** Szablicka, Monika  
**Subject:** RE: Concerning Your Case

Hi Monica,  
Can you please call me again. Another submitter called me right before you called.

Best regards,  
Gloria

---

**From:** Szablicka, Monika [<mailto:monika.szablicka@envigo.com>]  
**Sent:** Tuesday, March 28, 2017 4:50 AM  
**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>  
**Subject:** RE: Concerning Your Case

Dear Gloria,

Thank you for your reply. Yes I will call you at 9am EST (2pm UK time).

Kind regards  
Monika

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F +44 (0) 1480 892 362  
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---

**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]  
**Sent:** Monday, March 27, 2017 9:01 PM  
**To:** Szablicka, Monika  
**Subject:** RE: Concerning Your Case

Hi Monica,

I know it is very late your time. Would you be free to talk tomorrow at 9am EST to talk about your case. Unfortunately, I can't list the PMN number in an email to you as that is CBI.

Best regards,  
Gloria

---

**From:** Szablicka, Monika [<mailto:monika.szablicka@envigo.com>]  
**Sent:** Monday, March 27, 2017 11:58 AM  
**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>  
**Subject:** RE: Concerning Your Case

Dear Ms Odusote,

Thank you for contacting me. I have tried to calling you just now but I understand that you were not available. Please can you let me know which case number you were referring to in your email?

Thank you  
Kind regards  
Monika

Monika Szablicka  
Regulatory Specialist  
T +44 (0) 1480 892 439  
F +44 (0) 1480 892 362  
[envigo.com](http://envigo.com)



---

**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]

**Sent:** Monday, March 27, 2017 3:31 PM

**To:** Szablicka, Monika

**Subject:** EPA: Concerning Your Case

Hi Ms. Szablicka,

My name is Gloria Odusote and I am the Program Manager for your case. I would like to give you an update on your case.

Please call me at the number below at your earliest convenience.

Best regards,  
Gloria Odusote

Gloria Odusote  
Chemical Control Division  
EPA East  
1200 Pennsylvania Ave. NW  
Room 4133G, Mail Code 7405M  
Washington, DC 20460  
202 564-1845  
Fax 202 564 9490

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